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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/687,668 | 10/17/2003 | David W. Burke | 7404-555 | 9362 |

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

| EXAMINER | |
|---|---|
| SODERQUIST, ARLEN | |
| ART UNIT | PAPER NUMBER |
| 1797 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 02/28/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/687,668 | BURKE ET AL. | |
| | Examiner | Art Unit | |
| | Arlen Soderquist | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-12-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. For examination purposes the first through fourth AC signals as found in the claims will be treated as either applied sequentially or simultaneously. In other words four AC signals includes one AC signal having four different frequencies as well as four separate AC signals. Relative to the hematocrit estimation in claim 21, examiner will treat it as by any method including guessing or some other non-measurement method.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bodai (US 4,929,426). In the patent Bodai teaches a portable apparatus for measuring the electrochemical characteristics of a sample. A disposable cartridge, including a plurality of interconnected flow chambers, houses a printed circuit board substrate upon which reference and indicating electrodes are formed. The electrodes are employed in the presence of chemical reagents to aid in the electrochemical determination of a sample undergoing analysis. A thermal sensing element is in close proximity to the electrodes to permit the correction of the measurement for variations in temperature. After a pH value has been determined, the used cartridge can be mechanically ejected thus eliminating user exposure to the blood sample being measured. In this way, the pH of a blood sample can be determined quickly, effectively, inexpensively and with a minimum amount of sample and reagent preparation. Column 5, lines 56-60 discuss the temperature and other corrections. Element 42 is the temperature sensor. Column 7, lines 39-66 discuss the blood flow in the sample chamber and teach that the blood flows over both the measuring structure and the thermal sensor. The blood files the sample chamber (lines 63-67) so that there is intimate contact between the sample and both the measuring structure and temperature sensor at the time of measurement. Column 9, lines 42-49 discuss the presence of at least one reagent. The reagent appears to be capable of dissolving into the sample. Column 10, line 48 to column 11, line 7 discusses the temperature measurement and the application of a temperature correction to the measurement from each of the electrodes present in the device. Column 12, lines 45-49 clearly teach the presence of electrodes for measuring other parameters of the blood sample.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodai as applied to claim 1 above, and further in view of Diebold (US 5,437,999), Douglas (US 6,001,239), Drummond (US 5,863,400) or White ((US 5,243,516). Bodai does not teach the test strip format for the sensor.

In the patent Diebold teaches high-resolution, biocompatible electrodes allowing production of an electrochemical sensor which is capable of precise analyte concentration determination on a very small sample size. Electrically conducting material is affixed to a first insulating substrate. A second insulating substrate is then affixed to the electrically conducting material and patterned using photolithography to define an electrode area. Alternatively, the electrically conducting material may be screen printed directly onto a standard printed circuit board substrate in the case of a counter or reference electrode. In either case, the substrate may be rigid or flexible. When the electrodes produced in this way are then used in an electrochemical sensor which includes a reagent, the small and highly-defined electrode areas permit highly-accurate electrochemical analyte measurements to be performed on very small sample sizes. The reagent composition is given on column 10. Columns 12-13 give an example of use of the electrochemical sensor. Of note in this section is the measurement of the response of the sensor 10 seconds after applying the sample (see column 13, lines 2-8). Lines 9-16 of column 13 teach the contact between a meter measuring circuit and the sensor and the adaptation

of the meter to apply an algorithm to the current measurement to provide the level of the analyte. Lines 16-26 of column 13 list several meters that the sensor is to be used in combination with including that described in US Patent Number 5,243,516 which is incorporated by reference. Diebold does not teach that the meter has a timing circuit that causes the measurement of current at this time.

In the patent Douglas teaches an electrochemical test device for determining the presence or concentration of an analyte in an aqueous fluid sample. The electrochemical test device includes a working electrode and a counter electrode made of an amorphous semiconductor material. The working electrode is overlaid with a reagent capable of reacting with an analyte to produce a measurable change in potential that can be correlated to the concentration of the analyte in the fluid sample. The test device optionally contains a reference electrode made of an amorphous semiconductor material having a reference material on the reference electrode. Lines 1-25 of column 13 teach that the disclosed test device is inserted into a suitable meter that has a measuring circuit to apply an algorithm to the current measurement to provide the level of the analyte. This section lists several meters that the sensor is to be used in combination with including that described in US Patent Number 5,243,516 which is incorporated by reference. The section also teaches that a sample of blood is applied and the current is measured in about 10 to about 30 seconds after applying the sample. Douglas does not teach that the meter has a timing circuit that causes the measurement of current at this time.

In the patent Drummond teaches an electrochemical cell comprising a porous membrane (8) of electrically insulating composition, the membrane having pores communicating from one side of the membrane to the other, a working electrode (5) disposed on one side and a counter or pseudo-reference electrode (7) disposed on the other side. A target area (11) of one electrode is liquid permeable and extends over the surface of membrane (8) without blocking underlying pores of the membrane. Optional insulating layers (9,10) cover the electrodes (5,7) and an opening defines the target area (11). Preferably, the porous membrane is impregnated with reagents, for example GOD/Ferricyanide. The paragraph bridging columns 4-5 teaches that any electrochemically interfering substances will be present at substantially constant concentration throughout the test. In contrast, the reduced mediator concentration will build up in concentration as the test progresses. Therefore a voltage pulse at the start of the test will

measure predominantly the electrochemically interfering substance, whereas one at the end of the test will measure the electrochemically interfering substances plus the reduced mediator produced by turnover of the glucose. Subtraction of the first signal from the last will remove or reduce the effect of the electrochemically interfering substances. For example, an initial pulse of 0.1-10 seconds e.g. 2 seconds measures the effect of electrochemically interfering substances. A subsequent delay of 1 to 100 seconds e.g. 8 seconds (a total time of ten seconds) is effected by disconnecting the electrodes after which a further pulse again measures the effect of electrochemically interfering substances. However, there is now an increased glucose dependent current due to the accumulation of reduced mediator near the electrode. Column 5, lines 37-44 teach the electrochemical cell in various formats including a disposable strip.

In the White patent that is incorporated by reference by both Diebold and Douglas a biosensing instrument for quantitatively determining the concentration of an analyte (glucose, cholesterol) in a body fluid such as blood is taught. In column 6, lines 5-44 discuss the operation of the device including the microprocessor causing the voltage module to apply an autodrop potential to the electrochemical cell. When a sample or drop of blood is placed in the cell a spike of current occurs indicating the presence of the sample (sample is detected or sensed). At this point the microprocessor causes the autodrop potential to be removed for a time period followed by causing a measurement potential to be applied to the cell and records a current measurement.

It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the teachings of Bodai to other formats of portable analyzers as taught by Diebold, Douglas, Drummond or White because of the ability to correct for temperature and the benefits thereof for a number of different analysis assays as taught by Bodai.

6. Claims 5-17, 20 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodai alone and also in view of Diebold, Douglas, Drummond or White as applied to claims 1-4 above, and further in view of Doss and de Vries. Bodai is not clear on how the temperature is measured.

In the paper Doss discloses a hyperthermia applicator intended for complete implantation and long-term use. Radio frequency energy is transmitted from an external antenna to a closely coupled subdermal antenna. This internal antenna is connected via a transmission line to deeply implanted electrodes. Changes in temperature at the electrodes result in a change in tissue

resistivity which modifies the complex impedance seen at the external antenna terminals. This variation in antenna impedance (magnitude and/or phase angle) can, in principle, be utilized to indirectly monitor and regulate tissue temperature at the electrode location. Test results from conductive-gel tissue phantom experiments are presented.

In the paper de Vries discusses implications of the dielectrical behavior of human blood for continuous online measurement of hematocrit. A study was designed to explore the possibility of detecting the hematocrit of blood by means of admittance measurements. The admittance and phase angle of blood kept in a measuring cell were determined at various frequencies between 60 kHz and 24 MHz. A reliable and accurate estimation of hematocrit was obtained in two ways. First, low-frequency admittance, high-frequency admittance and a factor x, which was the conductive percentage of cell content, were used. Secondly, the maximum phase angle was used. Both methods can be applied to obtain continuous on-line information about hematocrit for blood volume control during hemodialysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the temperature measurement method of Doss and the hematocrit measurement method of de Vries into the Bodai method because of the ability to measure the temperature and hematocrit without providing anything more than the electrodes already present and an AC signal generator/analyzer as shown by Doss and de Vries.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-38 and 44-46 of U.S. Patent No. 6,645,368 in view of Bodai, Doss and de Vries as explained above. The instant claims are of a scope that encompasses the patented claims except for the type of correction that is made based on the AC signal. However, Bodai clearly indicates that temperature is one parameter that need to be taken into account and Doss and de Vries show the ability to measure the temperature and hematocrit without providing anything more than the electrodes already present and an AC signal generator/analyzer. Therefore it would have been obvious to incorporate these types of corrections because of the need to apply corrections of these types in analysis methods.

9. Applicant's arguments filed December 19, 2007 have been fully considered but they are not persuasive. Relative to the anticipation by Bodai, the arguments are not commensurate in scope with the claims. Examiner notes that there is no restriction on the type of structure used to make the temperature measurement. Thus a temperature sensor such as found in Bodai is within the scope of the instant claims as long as it is measuring the actual temperature of the sample in the reaction zone. The reaction zone of claim 1 is sort of defined as the volume in which the sample reacts with the reagent. Claim 3 is clear that this can constitute a capillary fill space (sample chamber). With this in mind, a temperature sensor placed in a sample chamber meets the scope of claim 1. Furthermore, Bodai is not set up with the typical temperature sensor that applicant is describing in the instant specification on page 38, lines 7-20. The sensor in Bodai is located in the sample chamber so that there is contact with the sample being measured. Thus it is the sample temperature that is being measured rather than a temperature that is adjacent to the sample chamber. Finally, it appears that the reagent of Bodai is dissolvable in the sample so that the sample chamber does in fact constitute the reaction zone of the claims.

Relative to the combination of references examiner points out that the instant claims are of a scope that all electrode configurations are included. It is also noted that at no point are the claims limited to exclude the presence of a DC signal. As a further response to applicant's argument that the electrode configurations are different, the test for obviousness is not whether

the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus one of ordinary skill in the art is perfectly capable of adapting the teachings of the secondary reference to the primary reference. These comments are also relevant the obviousness type double patenting rejection.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797